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REMARKS

Claims 1-7, 9-10, and 12-17 are presently pending. All pending claims were rejected. Claims 1-4, 7, and 16 are amended herein. Claims 2 and 3 are amended to correct typographical errors. Support for the amendments to claim 1 is found in Tables 1 and 2, column 2, lines 63-67, and column 13, lines 7-19. Support for the amendments to claims 4 and 7 are found at column 2, lines 63-67. Support for the amendment to claim 16 is found at column 19, line 60 to column 20, line 4. No new matter has been introduced and entry of the amendments is respectfully requested.

Applicants gratefully acknowledge that claims 1-7, 9-10, and 12-17 are properly viewed as in compliance with 35 U.S.C. § 101 as well as the Examiner's withdrawal of the finality of the last Action.

Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

Claims 1-7, 9-10, and 12-17 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to reasonably provide enablement for a nucleic acid encoding 132 contiguous amino acid sequences of SEQ ID NO:2, or 17 contiguous amino acids of SEQ ID NO:4, or 30 contiguous amino acids of SEQ ID NO:5, or a nucleic acid which hybridizes to SEQ ID NO:1 or 3 or a nucleic acid encoding an antigenic polypeptide of IL-B30 comprising 132 contiguous amino acids of SEQ ID NO:2, or 17 contiguous amino acids of SEQ ID NO:4, or 30 contiguous amino acids of SEQ ID NO:5, or a nucleic acid which hybridizes to SEQ ID NO:1 or 3. The Action asserts that the specification fails to provide sufficient guidance for the claimed invention because no actual or prophetic examples on expected performance parameters are disclosed for any of the possible muteins of IL-B30 and because no correlation between IL-B30 antigenicity and structure exists. Therefore, the Action concludes that the unpredictability of a mutation's effects on protein function requires undue experimentation to make and use the claimed invention. Applicant respectfully traverses this rejection for the reasons discussed below.

Applicant respectfully submits that the specification fully enables the claimed invention because the polynucleotide claims relate to specific sequences encoding full-length IL-B30 polypeptides of different species and thus no undue experimentation is required to make or use the invention. Claims 1 and 4, and the respective dependent claims, contain DNA sequences encoding a polypeptide comprising some portion of the amino acid sequence of IL-B30 disclosed in the specification. *See* SEQ ID NOs: 2, 4, and 5. Moreover, the DNA sequence is claimed in terms of a defined amino acid sequence and not in terms of a functional polypeptide (*i.e.*, biological activity). In other words, the DNA sequence is not limited to one that encodes any polypeptide that has the same biological function as IL-B30, but relates to the disclosed amino acid sequences. Therefore, performance parameters are not required to enable the claimed invention.

The specification also fully enables the genus of embodiments within the claimed invention because only routine experimentation is required to identify its numerous embodiments. Each embodiment can be readily identified using the genetic code because the claimed invention pertains to the disclosed amino acid sequences. It is routine for one of skill in the art to determine the identity of the genetic sequence for a particular amino acid. Likewise, the instant specification fully enables the polypeptides containing five or fewer conservative substitutions claimed in claim 16. The term "conservative substitutions" is a term of art recognized by a skilled artisan that limits the substitutions made in a particular polypeptide to a discreet set of amino acids with similar characteristics (*e.g.*, charge, size, hydrophobicity, *etc.*) of the disclosed amino acid such that overall functioning is not greatly affected. THE DICTIONARY OF CELL & MOLECULAR BIOLOGY 113 (J.M. Lackie *et al.*, Eds. 3d ed. 1999) Nonetheless, Applicant provides adequate guidance with regards to conservative substitutions in the instant specification. *See* column 14, lines 27-32. Therefore, only routine experimentation is required to identify the claimed embodiments. While some experimentation is required, it is not undue because it consists only of well known and conventional methods.

The findings of Voet *et al.* are not applicable because (1) the instant DNA sequence is not claimed in terms of its biological activity, and (2) the substitution of Voet is not conservative. Voet illustrates the potent effect of a radical amino acid substitution on polypeptide function by examining a single amino acid substitution of Glu (an acidic amino acid) for Val (a nonpolar amino acid). The substitution of Glu for Val is a non-conservative substitution resulting in a significant alteration in hemoglobin's functionality. Hence, Voet is not relevant to the instant invention.

Furthermore, the specification provides adequate guidance regarding the making and using of the invention. The making of the claimed DNA sequences is addressed by the specific procedures disclosed in the specification regarding the routine synthesis of DNA (*see, e.g.*, column 19, line 60 to column 24, line 12) and polypeptides (see, e.g., column 24, line 13 - column 25, line 20).

Finally, the claims of this invention are analogous to those discussed in the "Training Materials for Examining Patent Applications with Respect to 35 U.S.C. § 112, First Paragraph - Enablement in Chemical/Biotechnical Applications," Example N. *See* http://www.uspto.gov/web/offices/pac/dapp/oppd/1pecba.html. In the analysis of a claimed DNA sequence comprising a defined amino acid sequence, these materials state that no undue experimentation is required to practice the making and using of this large genus of DNA sequences because "each embodiment can be readily identified using the genetic code, synthesized using conventional methods, and used in the manner taught in the specification without undue experimentation." Therefore, "no enablement rejection should be made."

In light of the above remarks, Applicant respectfully submits that the enablement rejection under 35 U.S.C. § 112, first paragraph, is overcome. Therefore, Applicants request the withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description

Claims 1-7, 9-10, and 12-17 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to describe the subject matter in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. According to the Action, the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The Action also asserts that the genus is highly variant and lacks a description of identifying structural features. Applicant respectfully traverses this rejection for the reasons discussed below.

The genus of the claimed invention is sufficiently described in the specification to convey to one of ordinary skill in the art that Applicant had possession of the genus of sequences encoding IL-B30. First, the specification clearly describes the claimed sequences as a portion of the disclosed full-length sequence encoding IL-B30 isolated from human, mouse, and pig. *See, e.g.*, SEQ ID NOs:2, 4, and 5. Therefore, the distinguishing attribute and unifying feature of the claimed genus is a DNA sequence that encodes some specific portion of the disclosed IL-B30 protein. Second, the disclosure of the complete amino acid sequence would convey to one of skill in the art that Applicant was in possession of the encoding DNA sequence. Applicant explicitly discloses more than one species of the claimed genus of DNA sequences in the specification, thus demonstrating actual possession of the claimed genus at the time of filing. *See, e.g.,* SEQ ID NOs: 1 and 3 (disclosure of DNA sequence encoding human and mouse IL-B30). Third, while the genus encompasses a large number of embodiments, it is not unpredictably variant. The claimed sequence must encode at a portion of the disclosed amino acid sequence of IL-B30, and thus the variance is limited to that tolerated by the genetic variance in coding sequence for a particular amino acid in the disclosed sequence, and thus one of skill in the art would reasonably believe that Applicant had possession of the invention.

In light of the above remarks, Applicant respectfully submits that the written description rejection under 35 U.S.C. § 112, first paragraph, is overcome. Therefore, Applicants request the withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite in its recitation of the term "natural sequence." Claims 1 and 16 are rejected as vague and indefinite in the recitation of the term "mature." Claims 1 and 4 are rejected as vague and indefinite because it is not clear whether the encoded amino acid sequence must serve as the antigenic peptide. Claims 3-10, 12-15 and 17 are rejected insofar as they depend upon the above claims. Applicant respectfully traverses these rejections.

Claims 1 and 16 have been amended to recite a portion of the amino acid sequences identified in SEQ ID NOs: 2, 4, and 5 of the specification, thereby clarifying the term "mature."

Applicants respectfully submit that one of ordinary skill in the art would understand the term "natural sequence" when viewed in light of the instant disclosure. The specification discloses sequences as isolated from a natural source at column 19, line 60 to column 20, line 4. One of the disclosed natural sources is a mammal. Nonetheless, in an effort to expedite prosecution, claims 16 has been amended to recite a mammal as the source of the sequence.

Furthermore, Applicant respectfully submits that one of ordinary skill in the art would understand the encoded amino acid sequence of claims 1 and 4 serves as the target for an immune response because of the plain language of the claims and in light of the disclosure in the specification. Nonetheless, in an effort to expedite prosecution, claims 1, 4, and 7 have been amended.

In light of the above remarks, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, second paragraph, are overcome. Therefore, Applicants request the withdrawal of the rejection.

CONCLUSION

Applicants respectfully submit that the rejections under 35 U.S.C. § 112 have been overcome by the above remarks. Early allowance of pending claims 1-7, 9-10, and 12-17 is respectfully requested. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**". In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000201.

Respectfully submitted,

Dated: January 30, 2003 By: _____

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EXHIBIT A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Thrice Amended) An isolated or recombinant polynucleotide encoding a[n antigenic] polypeptide comprising:

a) at least [132]40 contiguous amino acids from [a mature coding portion] amino acids 1-168 of SEQ ID NO:2;

b) at least 17 contiguous amino acids from [a mature coding portion] amino acids 1-175 of SEQ ID NO:4; or

c) at least 30 contiguous amino acids from [a mature coding portion] amino acids 1-102 of SEQ ID NO:5.

2. (Amended) The polynucleotide of claim 1, enc[l]oding a [mature] polypeptide of:

c) SEQ ID NO:2;

d) SEQ ID NO:4; or

c) SEQ ID NO:5.

3. (Twice Amended) The polynucleotide of claim 1, which encodes amino residues 155-164 of SEQ ID NO:2 and hybridizes under stringent wash conditions of at least 65°C[.], less than about 150 mM salt to the complement of:

a) the open reading frame of SEQ ID NO[;]:1; or

b) the open reading frame of SEQ ID NO:3.

4. (Thrice Amended) An isolated or recombinant polynucleotide encoding a[n antigenic] polypeptide comprising at least 67 contiguous nucleotides of a coding portion of SEQ ID NO:3, wherein said contiguous nucleotides are from nucleotides 580-670 of SEQ ID NO:3.

7. (Amended) A method of making a[n antigenic] polypeptide comprising expressing said recombinant polynucleotide of claim 1 and isolating said polypeptide, thereby making said [antigenic] polypeptide.

16. (Twice Amended) The polynucleotide of claim 2, wherein said polynucleotide:

a) encodes a polypeptide with a [natural] sequence of [the mature coding portion] amino acids 1-168 of SEQ ID NO:2 or amino acids 1-175 of SEQ ID NO:4;

b) is isolated from a mammal [nature];

c) encodes a polypeptide comprising five or fewer conservative substitutions from a [natural] sequence of amino acids 1-168 of SEQ ID NO:2[or 4]; or

d) encodes a polypeptide comprising five or fewer conservative substitutions from a [natural] sequence of amino acids 1-175 of SEQ ID NO:4.